# This Page Is Inserted by IFW Operations and is not a part of the Official Record

# **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

## WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4:

A61M 16/12

A1

(11) International Publication Number:

WO 87/01599

(43) International Publication Date:

26 March 1987 (26.03.87)

(21) International Application Number: PCT/US86/01919

(22) International Filing Date: 15 September 1986 (15.09.86)

(31) Priority Application Number:

778,838

(32) Priority Date:

23 September 1985 (23.09.85)

(33) Priority Country:

US

(71) Applicant: BATTELLE DEVELOPMENT CORPORA-TION [US/US]; 505 King Avenue, Columbus, OH 43201-2693 (US).

(72) Inventors: DE VUONO, Anthony, C.; 246 Maple Drive, Columbus, OH 43228 (US). RAZGAITIS, Richard; 2070 West Lane Avenue, Columbus, OH 43221 (US).

(74) Agents: BISSELL, Barry, S. et al.; Battelle Development Corporation, 505 King Avenue, Columbus, OH 43201-2693 (US). (81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

#### Published

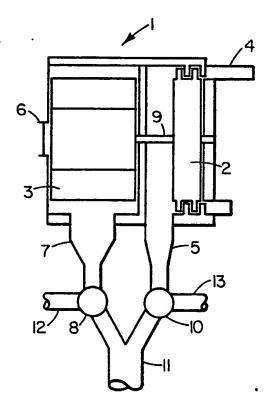
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: OXYGEN/AIR MIXTURE BLOWER FOR RESPIRATORY CARE

#### (57) Abstract

A respiratory care device utilizes pressurized oxygen to pump an oxygen/air mixture to the patient. The device comprises a coupled turbine and blower. The pressurized oxygen drives the turbine which pumps air through the blower. The oxygen may be mixed with the air in selected ratios and delivered to the patient. Droplets may be added to the oxygen, to the air or to the mixture, upstream or downstream of the device or within the device.



#### FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

	-					
AT	Austria	GA	Gabon		MR	Mauritania
ΑU	Australia	GB	United Kingdom		MW.	Malawi
BB	Barbados	HU	Hungary		NL	Netherlands
BE	Belgium	П	Italy		NO	Norway
BG.	Bulgaria	JP	Japan		RO	Romania
BR	Brazil	KP	Democratic People's Republic	_	SD	Sudan
CF	Central African Republic		of Korea	•	SE	Sweden
CG	Congo	KR	Republic of Korea		SN	Senegal
CH	Switzerland	LI	Liechtenstein		SU	Soviet Union
CM	Cameroon	LK	Sri Lanka		TD	Chad
DE	Germany, Federal Republic of	LU	Luxembourg		TG	Togo
DK	Denmark	MC	Monaco		US	United States of America
FI	Finland .	MG	Madagascar			
FR	France	ML	Mali			

Oxygen/air mixture blower for respiratory care.

#### Background of the Invention

Ourrent inhalation therapy requirements vary over a wide range. For example, high-oxygen concentration streams are occasionally required for short durations, but the longer term care generally demands low oxygen gas. But the total gas volume needs of the patient (air plus oxygen) remains nearly constant. These broad requirements necessitate an aspirator device with a high degree of flexibility in effecting the desired composition and flow rate.

Moreover, moderate back pressures caused by patient exhalation together with the use of long, small-diameter delivery tubes could beneficially be overcome by a device capable of providing necessary gas volumes.

#### Summary of the Invention

It is an object of the present invention to provide an aspirator which has the flexibility to deliver an air/oxygen mixture at nearly constant volume with an 20 easily selectable composition.

It is a further object to provide a device which can deliver the gas mixture at high or low flow rates.

It is also an object to provide a device for delivering the gas mixture at such pressure as to be able 25 to overcome the back pressures inherent in a patient delivery system using smaller-bore tubing than presently used.

It is finally an object to provide such a device which is of such simplicity and cost that it can be wholly 30 or partly disposable.

In accordance with the objectives, the invention is a method and apparatus for diluting a high-pressure oxygen stream with ambient air.

WO 87/01599 PCT/US86/01919

- 2 -

In its broadest sense, the invention comprises a device for causing high-pressure oxygen to do mechanical work to pump low pressure air and then mixing selected portions of the air and oxygen into a therapeutic mixture.

In a narrower sense, the invention comprises a gas turbine and blower coupled for rotation, means for directing a high-pressure oxygen stream to rotate the tubine, a source of air in communication with the blower such that the air is pumped by the blower upon rotation of 10 the turbine, and means for mixing selectable portions of the oxygen stream and pumped air for delivery to the patient.

#### Brief Description of the Drawings

Fig. 1 is a schematic view of the turbine/blower 15 device according to the invention.

Fig. 2 is a sectional elevation view through the internal parts of the turbine/blower device.

Fig. 3 is a side view of the device in Fig. 2 looking at the turbine.

#### 20 Description of the Invention

05

It would be desirable in the respiratory care field to be able to deliver large volumes of oxygen or an oxygen/air mixture to a patient at fairly high pressure and a constant composition. Currently the inability to do 25 this has resulted in the use of open patient masks and large diameter corrugated tubes which have a low back With this apparatus, a flow of 40-60 pressure. liters-per-minute (lpm) of gas can reach the patient but only 1-2 lpm are used, the rest is lost out the mask 30 openings. Moreover, since the gas is at fairly low pressure, liquid in the gas may rainout in the patient hose leaving a site for infectious organisms to grow. Antibiotics cannot be added to the gas without contaminating the entire area through the open mask.

The present device provides for the pumping of air or air/oxygen mixture at up to about 50 lpm and a pressure equal to 2-3 inches of water. This enables the use of a medium back pressure closed mask and small diameter delivery tube. The small quantities of gas (e.g. 1-2 lpm) that are genuinely needed can be delivered and maintained "on demand" because of the pressurization capability. The back pressure capability allows small—bore—tubing to be used which results in high gas velocities preventing rainout. It is also now possible to filter the gas (which requires a pressure drop) and to add antibiotics to the patient gas (since it is directed to a closed mask).

In general, the current technology involves using the high pressure (50 psi) oxygen stream in hospital rooms to aspirate air and liquid through venturi action (so called Bernoulli devices). This operation tends to limit oxygen concentration to about 27-28% minimum. The present invention proposes to more directly pump the room air by causing the oxygen to do mechanical work to run an air compressor and then mixing portions of the oxygen with the compressed air. The oxygen concentration could, of course, be reduced to that of the ambient air since no oxygen need be mixed in the final gas.

25 Fig. 1 shows a schematic of one embodiment of the invention. The aspirator device 1 comprises an oxygen turbine 2 mounted for rotation with a blower 3 through shaft 9. The turbine may be rotated by impulse or reaction by the oxygen stream entering through an orifice 4 and exiting through outlet 5. An impulse turbine is shown in the Figure. The blower pumps room air through entrance 6 out exit 7. Valve 8 allows a selectable portion of the air to be dumped through line 12 and a selected portion to be directed to the patient through delivery hose 11. Valve

10 allows spent oxygen from the turbine to be dumped through line 13 or delivered to the patient through line 11.

Pigs. 2 and 3 show more detail of the turbine/05 blower embodiment. A turbine housing consists of a circular front plate 21 joined to a back container 23. The
blower housing 25 is fixed to the back container 23 by
convenient means. Shaft 24 is fixed to the front plate and
extends axially through the turbine housing into the
10 blower housing. A cylindrical bearing 26 is rotatable on
the shaft 24. Turbine 22 and blower 27 are fixed for
rotation on the bearing 26.

Oxygen orifice 28 directs the oxygen stream against the turbine blades. Oxygen exit 29 exhausts the 15 spent oxygen. Air entrance 30 on the blower housing is in communication with room air to pump air through the device and out air outlet 31.

The turbine is preferably directly coupled to the blower without gears. It preferably has single stage, 20 backward-curved blades though other configurations may also be used. The blower is preferably a conventional, center-draw forward-blade fan. Typically, an orifice 0.2-0.5 mm in diameter can deliver 1-2 lpm oxygen to the turbine and rotate it at up to about 12,000 rpm delivering 25 air at about 50 lpm and 3 inches of water back pressure.

The aspirator is preferably disposable and made of plastic parts (except for the bearings and shaft). In this case oxygen from the turbine could be mixed with the compressed air. Alternatively, the turbine portion may be 30 designed to be reusable, allowing for use of better construction materials. The blower would be disposable since it has direct communication to the patient. In this case, the oxygen to the turbine would be bled from the main oxygen stream (only 1-2 lpm are needed) and any oxygen requirements for mixing with the air would be met with

fresh oxygen from the main stream. The main oxygen stream could enter the compressed gas downstream of the blower or could enter the blower with the ambient air at the air inlet.

Diquid or a liquid/medicament mixture may be added at any convenient point. For example, a conventional mist generator could be used to supply moisture to the air inlet on the blower. The main oxygen stream could also be used to lift and nebulize liquid in the conventional way for introduction to the blower air inlet or to the compressed gas downstream of the device.

The invention has been described particularly with respect to a turbine/blower device. In the broader sense, however, the invention envisions the use of any convenient device for converting the energy in the pressurized oxygen into useful mechanical energy to increase the pressure of low pressure, ambient air. For example, a reciprocating positive displacement pump, pressurized bottle, gear pump, hydraulic multiplier, vibrating membrane, or shear drag turbine could be used in place of the turbine. Unlike conventional Bernoulli the oxygen and air may be kept separate so that air itself may be delivered to the patient under slight pressure or a mixture of air and oxygen may be delivered.

#### 25 Examples of the Preferred Embodiment

An aspirator device such as shown in Figs. 2 and 3 was constructed. A 7.5 cm diameter turbine with back-ward-curved, single-stage blades was fixed in a housing. The housing back was made of aluminum while the face plate was a clear polycarbonate. The oxygen nozzle was about 0.4 mm in diameter. The turbine was mounted on a shaft and a porous bronze bearing.

The blower had a 14 CFM output. The impeller was contained in a light polycarbonate housing and coupled to the turbine through the bearing.

Three feet of patient hose (22 mm I.D.) was 05 attached to the air output. The spent oxygen from the turbine was mixed with the compressed air output. Table 1 shows the mixing results.

TABLE 1

		O <sub>2</sub> input (lpm)	Air Output (1pm)	Shaft speed (rpm)	0 <sub>2</sub> %
-	1	0.5	30.1	800	26.5
	2	1.0	43.2	1148	25.8
	3	1.3	51.4	1367	25.7
	4	1.5	56.8	1511	25.6
	5	2.0	69.4	1844	25.8
	6	2.5	80.2	2131	26.0
	7	2.7	85.6	2276	26.2

05

10

15

We Claim:

- A respiratory care device for delivering an oxygen-containing gas under positive pressure to a patient comprising:
- a source of high-pressure oxygen,
  - a source of air,
  - a rotatable gas turbine,
  - a rotatable blower coupled to the gas turbine for rotation therewith and having an air entrance communicating with the source of air to admit the air to the blower and an air exit for discharging the air from the blower,

means for utilizing at least a first portion of the high-pressure oxygen to rotate the turbine, and means for delivering the air from the blower air exit to the patient.

- 2. The respiratory care device of Claim 1 which further comprises means for mixing said first portion of the oxygen with the air prior to delivery to the patient.
- 3. The respiratory care device of Claim 2 which further comprises means for mixing a second portion of the oxygen with the air prior to delivery to the patient.
- 4. The respiratory care device of Claim 1 further comprising means for mixing a second portion of 25 the oxygen with the air prior to delivery to the patient.
  - 5. The respiratory care device of Claim 4 wherein the first and second portions of the oxygen are separate streams.

WO 87/01599 PCT/US86/01919

- 8 -

6. The respiratory care device of Claim 5 wherein the means for mixing the second portion of the oxygen is located upstream of the blower entrance.

- 7. The respiratory care device of Claim 5 05 wherein the means for mixing the second portion of the oxygen is located downstream of the blower exit.
  - 8. The respiratory care device of Claim 5 which further comprises means for adding liquid in droplet form to the air prior to delivery to the patient.
- 9. The respiratory care device of Claim 8 wherein the liquid droplets are added to the air in the blower.
- 10. A respiratory care device for diluting an oxygen stream at pressure P<sub>1</sub> with air at a lower pressure 15 P<sub>2</sub> and delivering an oxygen/air mixture to a patient at pressure P<sub>5</sub> comprising:

20

25

means for converting energy of at least a first portion of the oxygen stream at pressure  $P_1$  into mechanical work and resulting in an outlet oxygen stream at pressure  $P_3$ ,

compressor means coupled to the conversion means for utilizing the mechanical work output thereof to raise the pressure of at least a portion of the air to pressure P4, and

means for mixing the air output of the compressor means at pressure  $P_4$  with a second portion of the oxygen stream at pressure  $P_1$  and/or the first portion of the oxygen stream at pressure  $P_3$  to obtain a mixture at pressure  $P_5$ , and

means for delivering the mixture at pressure P<sub>5</sub> to the patient.

10

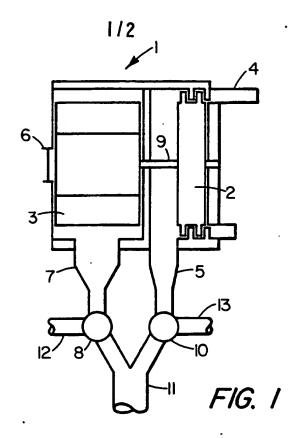
- 11. The respiratory care device of Claim 10 wherein the conversion means is a turbine.
- 12. The method for utilizing an oxygen stream at pressure P<sub>1</sub> and ambient air at a lower pressure P<sub>3</sub> to deliver an oxygen-containing gas under a positive pressure to a patient comprising:

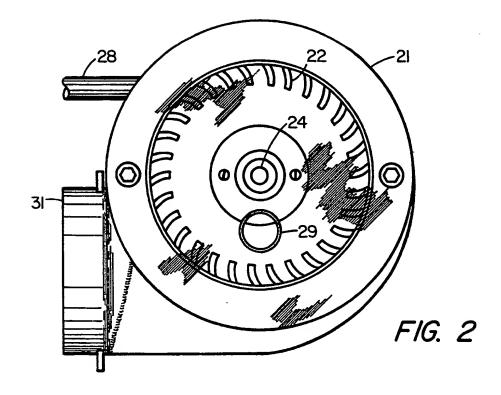
causing a first portion of the  $P_1$  oxygen stream to do mechanical work resulting in a reduction in pressure of the first portion of  $P_1$  oxygen to a pressure  $P_2$ ,

utilizing the mechanical work output of the first portion of the  $P_1$  oxygen stream to increase the pressure of the  $P_3$  air to a pressure  $P_4$ , and

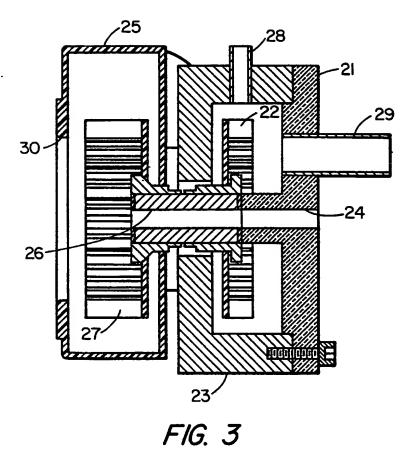
delivering a selected portion of the  $P_4$  air to the patient.

- 13. The respiratory care method of Claim 12 which further comprises mixing a second portion of the  $P_1$  oxygen stream at pressure  $P_1$  with the air prior delivery to the patient.
- 20 14. The respiratory care method of Claim 13 which further comprises adding liquid in droplet form to the air prior to delivery to the patient.





2/2



### INTERNATIONAL SEARCH REPORT

		International Application No	CT/US 86/01919				
L CLASSIFICATION OF SUBJECT MATTER (it several classification symbols apply, indicate all) *							
According to International Patent Classification (IPC) or to both National Classification and IPC							
IPC <sup>4</sup> : A 61 M 16/12							
II. FIELDS SEARCHED							
Minimum Documentation Searched 7							
Classification System	Classification System   Classification Symbols						
IPC <sup>4</sup>	A 61 M	•					
Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched **							
IIL DOCUMENTS	ONSIDERED TO BE RELEVANT						
Category •   Citat	ion of Document, 11 with Indication, where ap	propriate, of the relevant passages 12	Relevant to Claim No. 13				
1							
X DE	<pre>X DE, C, 893998 (O.P. BRAUN) 16 September 1954, see page 1, line 13; page 2, lines 17-46; figure 3</pre>						
Y		4-8,10,11,					
_	1962, see column 1, line 58						
A			2,3				
A DE	DE, A, 2613084 (FISHER & PAYKEL LTD) 21 October 1976, see page 4, lines 7-10						
A GB	, A, 1041313 (K.I. ED 1 Septembe 1966, se 23-32	1,12					
	···						
"T" later document published after the international filing date or priority data and not in conflict with the application but citied to understand the principle or theory underlying the invention."  "E" earlier document but published on or after the international filing date or priority data and not in conflict with the application but citied to understand the principle or theory underlying the invention.  "X" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means  "P" document published prior to the international filing date but later than the priority date claimed  "V" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "A" document member of the same patent family  IV. CERTIFICATION  Date of the Actual Completion of the International Search  Date of Malling of this International Search Report							
16th December 1986 2.8 JAN 1987							
13th December 1986							
International Searching Authority  Signature of Authorized Officer  EUROPEAN PATENT OFFICE  M. VAN MOL							

## ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO.

PCT/US 86/01919 (SA 14787)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 12/01/87

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	y Publication date
DE-C- 893998		None	
US-A- 3045668		None	
DE-A- 2613084	21/10/76	GB-A- 15	06684 12/04/78
GB-A- 1041313		FR-A- 14	04962